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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,917	12/12/2003	David James Dooley	PC 25870A	2382

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EXAMINER

CARR, DEBORAH D

ART UNIT	PAPER NUMBER
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1621

DATE MAILED: 04/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/734,917

Applicant(s)

DOOLEY ET AL.

Examiner

Deborah D. Carr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 9/2005.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Response to Arguments***

1. Applicant's arguments filed 23 January 2006 have been fully considered but they are not persuasive. The rejection of claims 1-24 under 35 USC§112, 1<sup>st</sup> paragraph is maintained.

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-24 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for fibromyalgia, does not reasonably provide enablement for all of the disorders cited in the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. While the specification enables for the treatment of fibromyalgia, there is no teaching about the treatment of these various disorders.

Applicant argues the examiner has not provided evidence or technical reasoning why one of ordinary skill in the art would question the enablement of the instant invention regarding its ability to treat said conditions.

The conclusion of lack of enablement was based on the evidence regarding each of the factors below, the specification, at the time the application was filed, would not have

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taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation.

These factors include:

- (A) The breadth of the claims;
- (B) The nature of the invention;
- © The state of the prior art;
- (D) The level of one of ordinary skill;
- (E) The level of predictability in the art;
- (F) The amount of direction provided by the inventor;
- (G) The existence of working examples; and
- (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

#### **The breadth of the claims**

Claims 1-24 are drawn to methods for treating disorders such as: OCD, phobias, PTSD, restless legs syndrome, premenstrual dysphoric disorder, hot flashes, fibromyalgia and its concomitant disorders, slow sleep wave n a patient by administering a compound of formula 1.

#### **The state of the prior art**

The examiner notes that the art of fibromyalgia and restless leg syndrome does not recognize any therapeutic agents that are known to fully treat these diseases. Applicants are invited to provide evidence to the contrary. In any event, the examiner notes that there is no art provided of record, evidence set forth in the disclosure, or correlation establishing some

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nexus to support administration or therapy between the art and the instant disclosure to support the alleged treatment applicability of the instant invention.

**The level of one of ordinary skill**

The skilled artisan in this field is that of an MD f and/or a PhD skilled in the development of therapeutics.

**The level of predictability in the art**

The examiner acknowledges the probability and predictability that the instantly compounds of formula 1 have applicability in treating said disease conditions. There is not seen sufficient data to substantiate the assertion that said instant diseases may be treated by the use of the compounds of formula 1. One skilled in this art would not predict from the disclosure provided that said instant diseases can be treated in view of the data and examples provided.

**The amount of direction provided by the inventor**

The instant specification is not seen to provide adequate guidance, which would allow the skilled artisan to extrapolate from the same to establish enablement for the treatment of said instant diseases. There is not seen guidance as to how the skilled artisan would formulate the requisite active agents and use it in methods for the treatment of a single disease. There is not seen sufficient guidance, which would teach the skilled artisan how to administer, said active agents in methods for treating said diseases including fibromyalgia.

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**The existence of working examples**

There are no examples drawn to the treatment of any instant disease states and there is not seen sufficient correlative data to substantiate the efficacy of any of the compounds made by the methods set forth in the instant disclosure to treat said diseased states.

**The quantity of experimentation needed to make or use the invention based on the content of the disclosure**

Indeed, in view of the information set forth supra, the instant disclosure is not seen to be sufficient to enable the treatment of any instant disease conditions including fibromyalgia and the skilled artisan would not extrapolate treatment efficacy from the results of the compounds of formula 1.

Based on the arguments supra, the rejection is being maintained.


2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah D. Carr whose telephone number is 571-272-0637. The examiner can normally be reached on Monday-Friday 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information

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for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



DEBORAH D. CARR  
PRIMARY EXAMINER

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